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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,937	11/07/2008	Victoria Yamazaki	54795-8003.US00	9737
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King & Spalding LLP P.O. Box 889 Belmont, CA 94002-0889			EXAMINER KIM, ALEXANDER D	
			ART UNIT	PAPER NUMBER
			1656	
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			06/08/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary**Application No.**

10/588,937

Applicant(s)

YAMAZAKI ET AL.

Examiner

ALEXANDER KIM

Art Unit

1656

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 March 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 7-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-848)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Application Status

1. In response to the previous Office action, a non-Final rejection (mailed on 10/25/2010), Applicants filed a response and amendment received on 03/25/2011. In said amendment, claims 1-5 are amended. Claims 1-14 are pending.

Previously, in view of election, claims 7-14 are withdrawn from consideration as non-elected inventions.

Claims 1-6 will be examined herein.

Withdrawn-Specification

2. The previous objection to the specification it contains an embedded hyperlink and/or other form of browser-executable code of "www.wikipedia.com", is withdrawn by virtue of applicants' amendment (see specification filed on 3/25/2011).

Withdrawn-Claim Objections

3. The previous objection of Claim 2 for reciting the abbreviation "GPI", is withdrawn by virtue of applicants' amendment.

4. The previous objection of Claim 3 for reciting "the 32 terminal amino acids..." without SEQ ID NO, is withdrawn by virtue of applicants' amendment.

5. The previous objection of Claim 4 for reciting the abbreviation "CHO", is withdrawn by virtue of applicants' amendment.

Claim Objections

6. Claims 1-6 are objected to because of the following informalities:

Claim 1 (Claims 2-6 dependent therefrom) recites "a sequence coding for an extracellular domain...". It should be ---a sequence encoding for an extracellular domain...---, to improve the format of claim 1.

Appropriate correction is required.

Withdrawn-Claim Rejections - 35 USC § 112

7. The previous rejection of Claim 1 (Claims 2-6 dependent therefrom) under of 35 U.S.C. 112, second paragraph, for reciting "5' signal sequence", "a purification epitope tag ...a 3' anchor sequence", is withdrawn by virtue of applicants' amendment.
8. The previous rejection of Claim 1 (Claims 2-6 dependent therefrom) under of 35 U.S.C. 112, second paragraph, for reciting "the extracellular domain" which has insufficient antecedent basis for this limitation in the claim, is withdrawn by virtue of applicants' amendment.
9. The previous rejection of Claim 3 under of 35 U.S.C. 112, second paragraph, for reciting "the 32 terminal amino acids of the GPI-anchoring sequence" which has

insufficient antecedent basis for this limitation in the claim, is withdrawn by virtue of applicants' amendment.

10. The previous rejection of Claims 1-6 under 35 U.S.C. § 112, first paragraph, written description, is withdrawn by virtue of reconsideration by the Examiner.

11. The previous rejection of Claims 1-6 under 35 U.S.C. § 112, first paragraph, scope of enablement, is withdrawn by virtue of reconsideration by the Examiner.

New and Maintained-Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 5 is rejected under of 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Instant rejection is necessitated by instant amendment.

Claim 5 recites "said signal sequence is an epidermal growth factor signal sequence". As written, the meets and bounds of said signal sequence and/or EGF signal sequence is wholly unclear since said signal can be any biological signal related to any epidermal growth factor. For example, the function of said signal sequence of EGF includes, but not limited to, secretion of EGF (as noted in page 10 of instant specification), an induction of growth of epidermal cell in animal, or any other related signal related to (or within biochemical pathway for) epidermal cell growth or a signal

sequence for producing EGF antibody, for example.

Appropriate correction and/or clarification is required.

12. The previous rejection of Claims 1-6 under 35 U.S.C. § 112, first paragraph, written description, is maintained.

Instant claim 5 recites "wherein said signal sequence is epidermal growth factor signal sequence" wherein instant claims 1-4 and 6 are broad or broader to encompass the limitation of claim 5; which includes, but not limited to, a native peptide signal sequence which directing the EGF to the secretion from mammalian cell which expresses said EGF.

Applicants argue that in view of instant specification reciting "epidermal growth factor (secreted)" on page 10, lines 4-5, applicants are in possession of claimed method of using the signal sequence of epidermal growth factor (EGF) (see middle of page 9, Remarks filed on 3/25/2011).

Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons. The Examiner acknowledges that EGF is well known small 6400 Da protein secreted into plasma and circulates in the blood by mammal for its function (see, for example, Burwen et al. Transport of Epidermal Growth Factor by Rat Liver: Evidence for Nonlysosomal Pathway, The Journal of Cell Biology, 1984, Vol. 99, pages 1259-1265). However, as noted previously, prior art and instant specification do not disclose single example of secretion signal sequence (that is peptide or nucleic acid encoding said peptide, naturally, recombinantly) from a native

EGF peptide sequence and having function of directing its fused partner to be exported outside the recombinant host cell once the fusion protein is produced by recombinant biotechnology. Applicants and prior art do not describe any structure of epidermal growth factor signal sequence in correlation with a function as export signaling peptide sequence; in turn there is no correlation between structure and function of the nucleic acid sequence encoding said any epidermal growth factor. Because the claims encompasses a method of using epidermal growth factor structure which do not function as signaling peptide, the one skilled in the art would not be in possession of full scope of the claimed genus of the instant specification.

13. The previous rejection of Claims 1-6 under 35 U.S.C. 112, first paragraph, scope of enablement, because the specification, is maintained for reasons below.

As noted previously, claims 1-4 and 6 are included since it contains scope of instant claim 5 reciting "wherein said signal sequence is epidermal growth factor signal sequence".

Applicants argue that in view of instant amendment in claim 5, instant rejection should be withdrawn. See top of page 10, Remarks filed on 3/25/2011.

Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons. The Examiner acknowledges that EGF is well known small 6400 Da protein secreted into plasma and circulates in the blood by mammal for its function (see, for example, Burwen et al. Transport of Epidermal Growth Factor by Rat Liver: Evidence for Nonlysosomal Pathway, The Journal of Cell Biology,

1984, Vol. 99, pages 1259-1265). However, as noted previously, prior art and instant specification do not disclose any direction or guidance to make a fusion protein containing an EGF signal sequence and use for directing its fused partner to be exported outside the recombinant host cell once the fusion protein is produced by recombinant biotechnology. The instant specification do not disclose a single working example of nucleic acid molecule encoding EGF signal sequence. Thus, it is unpredictable to make and use the claimed nucleic acid encoding any EGF signal sequence as a signal sequence in claimed method. The said unpredictability makes the relative skill required in the art very high. For all of the above reason, it would require undue experimentation necessary for claimed recombinant nucleic acid.

Maintained-Claim Rejections - 35 USC § 102

14. The previous rejection of Claim 3 under 35 U.S.C. 102(b) as being anticipated by Fayen et al. (Methods in Enzymology, 2000, Vol. 327, pages 351-368) is withdrawn by virtue of applicants' amendment.

Maintained-Claim Rejections - 35 USC § 102

15. The previous rejection of Claims 1 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Kingsman et al. (WO03/089649; Published Oct. 30, 2003; as cited in the IDS) is maintained for reasons stated below.

Applicants argue that Kingsman et al. "fail to teach at least a method including the step of displaying the anchor tethered protein on a lipid bilayer array or purifying and

reconstituting the anchor tethered protein in membranes for displaying on a lipid bilayer array. Kingsman et al. teach their method may be used for screening using phage display techniques or transformed host cells (pages 56-57)." (see bottom of page 11, Remarks filed on 3/25/2011)

Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons. It is noted that "for displaying on a lipid bilayer array" is an intended use of claimed active step of "purifying and reconstituting the anchor tethered protein in membranes" which do not have to be part of claimed said active step. Thus, step of "purifying and reconstituting the anchor tethered protein in membranes" encompasses any purification (to any degree, for example) and reconstituting (adding any buffer, for example) said anchor tethered protein in membranes of host cell, for example. As noted previously, anchor polypeptide includes, but not limited to, a membrane binding domain polypeptide.

Kingsman et al. further teach that solubilized purified protein either extracted from expressing mammalian cells or from transformed eukaryotic which allows for molecular binding assay with ability to automate, and high drug test throughput (see page 57, lines 6-10) wherein a purification inherently involves purification and/or adding appropriate buffer (e.g., reconstituting); meeting the added limitation of purifying and reconstituting the anchor tethered protein in membranes. For all the reasons above, instant rejection is maintained.

As noted in the previous office action, Kingsman et al. teach an expression vector, methods of use and products obtained therefrom (see top of page 1); wherein

the method of use which comprises (a) providing an expression vector (b) transfecting a host cell with the expression vector (see claim 11 and 12 on page 68, for example); wherein the host cell includes CHO mammalian cells (see page 22, line 12). The expression vector by Kingsman et al. includes "an expression vector comprising an amino-terminal tag sequence and a signal sequence operably linked to a nucleotide sequence of interest" (see page 4, lines 12-14); wherein the gene of interest includes the h5T4 human protein with or without the transmembrane domain (see Figure 2 and its description of Figure 2 on page 7). The term "anchor" has been defined as "a sequence for attaching or associating a membrane protein domain with a lipid or lipid bilayer" (see page 4, lines 12-13); thus, includes, but not limited to, any transmembrane domain which associates with lipid bilayer of cell. The "extracellular domain" and transmembrane domain (TM) as shown Figure 2 of Kingsman et al. meet the instant "extracellular domain" and instant "anchor sequence" in instant claim 1, respectively.

16. The previous rejection of Claims 1, 2, 4 and 6 under 35 U.S.C. 102(b) as being anticipated by Fayen et al. (Methods in Enzymology, 2000, Vol. 327, pages 351-368; as cited previously) is maintained.

Applicants argue that Fayen et al. "fail to teach at least a method including the step of displaying the anchor tethered protein on a lipid bilayer array or purifying and reconstituting the anchor tethered protein in membranes for displaying on a lipid bilayer array" (see bottom of page 11, Remarks filed on 3/25/2011)

Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons. As noted above, it is noted that "for displaying on a lipid bilayer array" is an intended use of claimed active step of "purifying and reconstituting the anchor tethered protein in membranes" which do not have to be part of claimed said active step. Thus, step of "purifying and reconstituting the anchor tethered protein in membranes" encompasses any purification (to any degree, for example) and reconstituting (adding any buffer, for example) said anchor tethered protein in membranes of host cell, for example. As noted previously, anchor polypeptide includes, but not limited to, a membrane binding domain polypeptide.

Fayen et al. also teach GPI-anchored fusion protein "allows the evaluation of the function of that domain after incorporation of the isolated protein into any cell target" (for example, see page 361, lines 19-20), wherein the isolation inherently involves purification as well as reconstituting as they are incorporated into said cell target membrane. For all the reasons above, instant rejection is maintained.

As noted in the previous office action, Fayen et al. teach a recombinant fusion protein production by method involving a preparation of "Chimeric cDNAs encoding GPI-modified polypeptides can be prepared by several approaches" (see page 355, lines 8-9) such as engineering by polymerase chain reaction (PCR)-based splice by overlap extension as shown in a vector of Fig 2 (see page 355, lines 13-14). Fayen et al. teach the use of "an expression vector upstream of the GPI-signaling sequence of DAF on page 362, lines 6-7, for example, which was expressed on the surface of transfected cells. Fayen et al. teach CHO mammalian cell line one of most widely

employed cell lines for GPI anchored protein production (see bottom, page 358). Fayen et al. teach "It is critical that the polypeptide fusion partner selected for GPI anchoring have an N-terminal signal peptide that initially directs it into the lumen of the ER" that is 5' signal in a corresponding DNA (see page 355, lines 17-19) and teach an example of hybrid DNA in Fig. 3 having CD8 α (the extracellular domain), his6 and DAF GPI modifying sequence expressing GPI-modified CD8 α -His6 fusion protein at the surface of transfected cells (see Fig3 and its description on page 367). Fayen et al. also teach "Because the polypeptide of interest must have an N-terminal signal sequence, a substitute signal sequence (e.g., that of oncostatin M) can be appended to the N-terminal sequence of the polypeptide", and CD8 α has intercellular adhesion domain of v-homology domain (see middle and bottom of page 361). Thus, the method disclosed in Fayen et al. meets all limitations of claims 1, 2, 4 and 6. Because, the 32 terminal amino acid of the GPI-anchoring sequence is unclear as noted in rejection above under 35 U.S.C. 112, second paragraph; and no amino acid sequence structure is required in claim 3; claim 3 is included in instant rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. Claims 1, 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kingsman et al. (WO03/089649; Published Oct. 30, 2003; as cited in the IDS) **in view of** Groves et al. (USPAP 20020160505; Pub. Date: Oct. 31, 2002), Groves et al. (Micropatterning Fluid Lipid Bilayers on Solid Support, Science, 1997, Vol. 275, pages 651-653), Cooper (Optical Biosensors in Drug Discovery, Nature Reviews Drug Discovery, 2002, Vol. 1, pages 515-528) and McCarthy et al. (US Patent 6,391,586; May 21, 2002). Instant rejection is necessitated by added limitation of claim 1.

The teachings of Kingsman et al. is noted above.

Kingsman et al. **do not** teach step of displaying the expressed fusion protein of interest on a lipid bilayer array.

It is well known to utilize lipid bilayer coated substrate (a lipid bilayer array, for example) attached, or purified and reconstituted with the expressed protein of interest with attached membrane binding entity (e.g., membrane anchor polypeptide) for automated and or high drug test throughput assay at the time of instant invention as exemplified by USPAP 20020160505 by Groves et al, Groves et al. (2002) and Cooper et al. For example, the USPAP 20020160505 discloses a lipid bilayer array (see Figure 1-2, for example) for reconstituting with recombinant cell (i.e., expressing protein of interest in membrane) or with membrane proteins into supported membranes; and method of using the array for a biochemical assay and detection throughout the disclosure. Groves et al. teach a lipid bilayer array (i.e., lipid bilayer supported membrane; and a method of using thereof, see Fig. 1 on page 652) that is "resembling those of living cells" and useful "for the study of physical and biological properties of

membranes" wherein it is well known that living membrane layer contains membrane proteins critical for cellular functions. Groves et al. also teach that the lipid bilayer array can be used for "incorporation of membrane proteins" (see left column, lines 27-28, page 652); and teaches purified protein can be incorporated into a supported membrane (see bottom of middle column, page 653). Furthermore, a lipid bilayer array technique "is analogous to phage display, except that here the peptide sequence is defined by its location in the array, thus, providing "immediate identification" (see page 653, middle column, lines 41-45).

Also, Cooper et al. discloses method of drug discovery using optical biosensors, for example, on a chip coated with tethered lipid bilayer (see bottom right column on page 523; and Figure 5, page 524) wherein these optical biosensor arrays (see Figure 6) "allowed a massive improvement in assay throughput with a high level of flexibility in experimental design" (see bottom of left column, page 526).

McCarthy et al. teach a recombinant method of producing fusion protein to be secreted and membrane protein and teach "The bold and under lined portion is the membrane anchor sequence" (see description of Fig. 3 on column 5, top) which is the last 32 amino acid sequence of SEQ ID NO: 2 (i.e., 32 amino acids long which is identical to instant SEQ ID NO: 3; see alignment below).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to recombinantly prepare and isolate a fusion protein(s) of interest comprising membrane binding domain by Kingsman et al.; and incorporate into a lipid bilayer array of Groves et al. (or Cooper 2002) including the GPI

anchor sequence of instant SEQ ID NO:3 with a reasonable expectation of success because Groves et al. teach said lipid bilayer can be used to incorporate biomolecule such as protein(s) with affinity to lipid bilayer as noted above. The motivation to do so is disclosed by Groves et al. who teach the lipid bilayer array "is analogous to phage display, except that here the peptide sequence is defined by its location in the array [as applicants have acknowledged, using "phage display techniques or transformed host cells (page 56-57)" (see Remarks filed on 3/25/2011, page 11, bottom)] thus, providing immediate identification." providing "new opportunities for the study of physical and biological properties of membranes" (see page 653, middle column, lines 32-34 and lines 38-42 in Groves et al.). Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

18. Claims 1-4 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fayen et al. (Methods in Enzymology, 2000, Vol. 327, pages 351-368; as cited previously) **in view of** Groves et al. (USPAP 20020160505; Pub. Date: Oct. 31, 2002), Groves et al. (Micropatterning Fluid Lipid Bilayers on Solid Support, Science, 1997, Vol. 275, pages 651-653), Cooper (Optical Biosensors in Drug Discovery, Nature Reviews Drug Discovery, 2002, Vol. 1, pages 515-528) and McCarthy et al. (US Patent 6,391,586; May 21, 2002). Instant rejection is necessitated by added limitation of claim 1.

The teachings of Fayen et al. is noted above.

Fayen et al. **do not** teach step of displaying the expressed fusion protein of interest on a lipid bilayer array.

It is well known to utilize lipid bilayer coated substrate (a lipid bilayer array, for example) attached, or purified and reconstituted with the expressed protein of interest with attached membrane binding entity (e.g., membrane anchor polypeptide) for automated and or high drug test throughput assay at the time of instant invention as exemplified by USPAP 20020160505 by Groves et al, Groves et al. (2002) and Cooper et al. For example, the USPAP 20020160505 discloses a lipid bilayer array (see Figure 1-2, for example) for reconstituting with recombinant cell (i.e., expressing protein of interest in membrane) or with membrane proteins into supported membranes; and method of using the array for a biochemical assay and detection throughout the disclosure. Groves et al. teach a lipid bilayer array (i.e., lipid bilayer supported membrane; and a method of using thereof, see Fig. 1 on page 652) that is "resembling those of living cells" and useful "for the study of physical and biological properties of membranes" wherein it is well known that living membrane layer contains membrane proteins critical for cellular functions. Groves et al. also teach that the lipid bilayer array can be used for "incorporation of membrane proteins" (see left column, lines 27-28, page 652); and teaches purified protein can be incorporated into a supported membrane (see bottom of middle column, page 653). Furthermore, a lipid bilayer array technique "is analogous to phage display, except that here the peptide sequence is defined by its location in the array, thus, providing "immediate identification" (see page 653, middle column, lines 41-45).

Also, Cooper et al. discloses method of drug discovery using optical biosensors, for example, on a chip coated with tethered lipid bilayer (see bottom right column on page 523; and Figure 5, page 524) wherein these optical biosensor arrays (see Figure 6) "allowed a massive improvement in assay throughput with a high level of flexibility in experimental design" (see bottom of left column, page 526).

McCarthy et al. teach a recombinant method of producing fusion protein to be secreted and membrane protein and teach "The bold and under lined portion is the membrane anchor sequence" (see description of Fig. 3 on column 5, top) which is the last 32 amino acid sequence of SEQ ID NO: 2 (i.e., 32 amino acids long which is identical to instant SEQ ID NO: 3; see alignment below).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to recombinantly prepare and isolate a fusion protein(s) of interest comprising membrane binding domain by Fayen et al.; and incorporate into a lipid bilayer array of Groves et al. (or Cooper 2002) including GPI-anchor sequence of SEQ ID NO: 3 with a reasonable expectation of success because Groves et al. teach said lipid bilayer can be used to incorporate biomolecule such as protein(s) with affinity to lipid bilayer as noted above. The motivation to do so is disclosed by Groves et al. who teach the lipid bilayer array "is analogous to phage display, except that here the peptide sequence is defined by its location in the array [as applicants have acknowledged, using "phage display techniques or transformed host cells (page 56-57)" (see Remarks filed on 3/25/2011, page 11, bottom)] thus, providing immediate identification." providing "new opportunities for the study of physical and

biological properties of membranes" (see page 653, middle column, lines 32-34 and lines 38-42 in Groves et al.). Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

Conclusion

19. Claims 1-6 are not allowed for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered section in this Office action to be fully responsive in prosecution.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEXANDER KIM whose telephone number is (571)272-5266. The examiner can normally be reached on 9AM-5:30PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on (571) 272-0939939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alexander D Kim/
Primary Examiner, Art Unit 1656

Art Unit: 1656

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RESULT 14
US-09-707-802-2
; Sequence 2, Application US/09707802
; Patent No. 6391586
;
; GENERAL INFORMATION:
;
; APPLICANT: McCarthy, Sean A.
;           Gearing, David F.
;           Levinson, Douglas A.
;
; TITLE OF INVENTION: METHOD FOR IDENTIFYING GENES
;                   ENCODING NOVEL SECRETED OR MEMBRANE-ASSOCIATED PROTEIN
;
; NUMBER OF SEQUENCES: 14
; CORRESPONDENCE ADDRESS:
;
; ADDRESSEE: Fish & Richardson, P.C.
; STREET: 225 Franklin Street
; CITY: Boston
; STATE: MA
; COUNTRY: US
; ZIP: 02110-2804
;
; COMPUTER READABLE FORM:
;
; MEDIUM TYPE: Diskette
; COMPUTER: IBM Compatible
; OPERATING SYSTEM: Windows95
; SOFTWARE: FastSeq for Windows Version 2.0
;
; CURRENT APPLICATION DATA:
;
; APPLICATION NUMBER: US/09/707,802
; FILING DATE: 07-No. 6391586-2000
; CLASSIFICATION: <Unknown>
;
; PRIOR APPLICATION DATA:
;
; APPLICATION NUMBER: 08/752,307
; FILING DATE: <Unknown>
;
; ATTORNEY/AGENT INFORMATION:
;
; NAME: Meiklejohn, Ph.D., Anita L.
; REGISTRATION NUMBER: 35,283
; REFERENCE/DOCKET NUMBER: 09404/020001
;
; TELECOMMUNICATION INFORMATION:
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; TELEPHONE: 617-542-5070
; TELEFAX: 617-542-8906
; TELEX: 200154
;
; INFORMATION FOR SEQ ID NO: 2:
; SEQUENCE CHARACTERISTICS:
;
; LENGTH: 530 amino acids
; TYPE: amino acid
; TOPOLOGY: linear
; MOLECULE TYPE: protein
; SEQUENCE DESCRIPTION: SEQ ID NO: 2:
US-09-707-802-2

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Query Match 100.0%; Score 157; DB 2; Length 530;
Best Local Similarity 100.0%;
Matches 32; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

[illegible]